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Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

UPDATE: EXCESSIVE MEDICARE REIMBURSEMENT FOR ALBUTEROL

Inspector General

January 2004
OEI-03-03-00510

Office of Inspector General

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EXECUTIVE SUMMARY

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for albuterol to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Albuterol is an inhalation drug commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Prior to 2004, Medicare's reimbursement methodology for albuterol and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, reimbursement for a covered drug was set at 95 percent of the drug's average wholesale price (AWP). Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 lowered reimbursement for many Part B drugs, including albuterol. In 2004, Medicare reimbursement for albuterol will be 80 percent of AWP.

Medicare beneficiaries are responsible for paying a 20 percent coinsurance payment for covered drugs. In calendar year (CY) 2002, Medicare and its beneficiaries paid $412 million for the unit-dose solution form of albuterol, up from $296 million in CY 2000.

Albuterol is usually provided to Medicare beneficiaries by pharmacies, which then submit claims for reimbursement to Medicare. Medicaid beneficiaries also obtain albuterol through pharmacies. Pharmacies can purchase drug products through group purchasing organizations (GPOs), wholesalers, and directly from manufacturers. Unlike Medicare and Medicaid, VA provides veterans with drugs purchased directly from manufacturers or wholesalers. There are several purchase options available to VA, including the Federal Supply Schedule, blanket purchase agreements, and VA national contracts.

We obtained Medicare's CY 2003 reimbursement amount for albuterol. For comparison, we: (1) obtained Medicaid's 2003 reimbursement amount for albuterol by reviewing the Federal Upper Limit list, (2) estimated 2003 pharmacy acquisition costs

for albuterol by obtaining pricing information from a national wholesaler/distributor and a GPO, and (3) determined the VA's 2003 payment amount for albuterol by accessing pricing data available on its website. We also obtained manufacturer-reported wholesale acquisition costs (WACs) from the January 2003 edition of the *Drug Topics Red Book*. We calculated potential savings by multiplying Medicare's 2002 total payments for albuterol by the percentage difference between the Medicare reimbursement amount and the Medicaid reimbursement amount.

The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for albuterol was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit Amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse albuterol at the Federal Upper Limit amount.

FINDINGS

Medicare continues to pay more for albuterol than other payors, costing the program and its beneficiaries millions of dollars a year. In 2003, the Centers for Medicare & Medicaid Services (CMS) set the Medicaid Federal Upper Limit amount for albuterol at $0.17 per milligram (mg), compared to $0.47 per mg for Medicare. If Medicare could reimburse for albuterol at the Federal Upper Limit amount, the program would have saved $263 million in 2002. Approximately $53 million of the savings would have resulted from reduced coinsurance payments.

Data collected from a drug wholesaler/distributor and a GPO showed that pharmacies were able to purchase albuterol for substantially less than the Medicare reimbursement amount. In spring 2003, the median price of albuterol at both the wholesaler/distributor and GPO was $0.06 per mg. Medicare's reimbursement amount of $0.47 per mg was nearly eight times more for the same amount of the drug. We did not collect data from pharmacies regarding any additional costs related to providing albuterol to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase albuterol for prices substantially below the Medicare reimbursement amount. In January 2003, the median WAC reported in the *Red Book* was $0.08 per mg.

If Medicare were able to use prices available to the supplier community as a basis for albuterol reimbursement, the program and its beneficiaries would save millions of dollars a year.

Since our 2002 report, which was based on 2001 data, the price at which albuterol was available to the supplier community had decreased, while the Medicare reimbursement amount had remained the same. In 2001, we calculated that the median price of albuterol through wholesaler/distributors and GPOs was $0.08 per mg, 33 percent higher than the 2003 price of $0.06 per mg. In addition, manufacturer-reported WACs had also decreased, from a median of $0.11 per mg in 2001 to $0.08 in 2003.

The median Federal Supply Schedule price available to VA for generic albuterol was $0.05 per mg. In comparison, Medicare reimbursed over 9 times more ($0.47 per mg) for the same amount of the drug in 2003. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug. Both the VA Federal Supply Schedule price and the Medicare reimbursement amount for albuterol have remained constant since our previous report.

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high premium for albuterol. This report is part of a series of reports on albuterol that have consistently found that the published average wholesale prices, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published average wholesale prices, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for albuterol

than they did several years ago. In addition, Medicare's total reimbursement for albuterol continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, albuterol is usually provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs, while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-ninth of Medicare's reimbursement amount is disconcerting.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including albuterol. Based on this new Act, Medicare will reimburse albuterol at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

TABLE OF CONTENTS

contracts are awarded to companies to provide supplies over a given period of time at the Federal Supply Schedule price. However, VA is sometimes able to negotiate prices lower than Federal Supply Schedule amounts through other avenues, such as blanket purchase agreements and VA national contracts.

Related Work on Albuterol

OIG has consistently found that Medicare's usual reimbursement amount for albuterol (based on AWP) is excessive. For example, in our report *Excessive Medicare Reimbursement for Albuterol* (March 2002), we calculated that the Medicare reimbursement amount for albuterol in 2000 was more than 9 times higher than the VA purchase price, and nearly 6 times the actual acquisition cost to pharmacies. According to our findings, excessive reimbursement for albuterol alone was costing Medicare and its beneficiaries up to $264 million per year.

In another of our reports, *Medicare Reimbursement for Albuterol* (June 2000), we found that Medicare would have saved almost $120 million in 1999 by reimbursing for albuterol at the amount paid by Medicaid.

In addition to the OIG, GAO has also found that Medicare reimbursement for albuterol is excessive. In its September 2001 report, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118), GAO found that the average widely available price to pharmacies for albuterol was 85 percent below the published AWP of the drug.

METHODOLOGY

We reviewed laws and regulations concerning Medicare drug reimbursement. We accessed CMS's Part B Extract Summary System to determine Medicare's total payments for the unit-dose solution form of albuterol in CY 2002. We obtained Medicare's CY 2003 reimbursement amounts for albuterol from all 4 DMERCs.

To determine Medicaid's 2003 reimbursement amount for albuterol, we obtained pricing information for the drug from the Medicaid Federal Upper Limit list.

To estimate pharmacy acquisition costs for albuterol, we obtained spring 2003 pricing information for albuterol from a

national wholesaler/distributor and from a GPO. As an additional estimate of pharmacy acquisition costs, we also obtained manufacturer-reported WACs from the January 2003 edition of the *Red Book*. The *Red Book* defines WAC as manufacturer-quoted list prices to wholesale distributors. These prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

To determine the VA's 2003 payment amounts for albuterol, we accessed a file on their website that lists prices available to the agency through the Federal Supply Schedule.

To calculate potential Medicare savings based on Medicaid, we compared Medicare's reimbursement amount for 1 mg of albuterol to the Medicaid Federal Upper Limit amount. We determined the percentage difference in price by subtracting Medicaid's price from Medicare's price and then dividing the result by the Medicare price. This percentage indicates how much Medicare would save if the program could base reimbursement on the Medicaid Federal Upper Limit amount. We then multiplied the percentage difference by the total amount Medicare paid for albuterol in 2002 to calculate dollar savings.

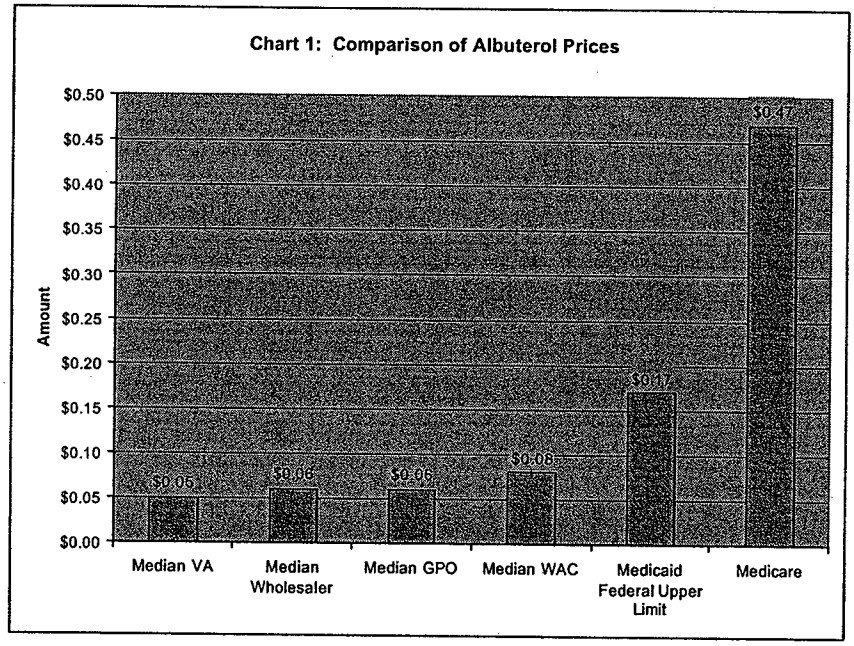
The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for albuterol was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse albuterol at the Federal Upper Limit amount.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the Presidents Council on Integrity and Efficiency.

FINDINGS

In 2003, Medicare reimbursed $0.47 per mg for albuterol, an amount that was considerably higher than the reimbursement amounts of other Government payers and the prices available to the supplier community. If Medicare were able to base its reimbursement amount for albuterol on prices available to these sources, the program and its beneficiaries could have saved millions of dollars in 2002. Chart 1 below compares the Medicare reimbursement amount to prices available to Medicaid, the supplier community, and VA.

Medicare continues to pay more for albuterol than other payers, costing the program and its beneficiaries millions of dollars a year.



Source: VA website, OIG survey of pharmacy prices, 2003 *Red Book*, Medicaid Federal Upper Limit list, and DMERC pricing publications.

Medicare and its beneficiaries would have saved $263 million in 2002 if the program were able to reimburse albuterol at the Medicaid Federal Upper Limit amount.

CMS sets the Medicaid Federal Upper Limit amount for albuterol at $0.17 per mg, compared to $0.47 per mg for Medicare. If Medicare were able to reimburse for albuterol at the Medicaid Federal Upper Limit amount, the program would have saved $263 million in 2002. Approximately $53 million of the savings would have had a direct

impact on Medicare beneficiaries in the form of reduced coinsurance payments.

The Medicare reimbursement amount for albuterol was eight times higher than the median price available to the supplier community.

Data collected from a drug wholesaler and a GPO showed that pharmacies were able to purchase albuterol for substantially less than the Medicare reimbursement amount. In spring 2003, the unit-dose solution form of albuterol was available from these sources at prices ranging from a low of $0.05 per mg to a high of $0.10 per mg. The median price of albuterol at both the wholesaler/distributor and GPO was $0.06 per mg. Medicare's reimbursement amount of $0.47 per mg was nearly eight times more for the same amount of the drug.

Pharmacies were able to acquire albuterol for less than a Medicare beneficiary would pay in coinsurance alone ($0.09 per mg). For example, a beneficiary using a typical monthly supply of albuterol (250 mg) would pay $23.50 in Medicare coinsurance. Through the sources we identified, pharmacies, on average, would pay just $15.00 for the same supply. We did not collect data from pharmacies regarding any additional costs related to providing albuterol to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase albuterol for prices substantially below Medicare. In January 2003, the median WAC reported in the *Red Book* was $0.08 per mg. The *Red Book* defines WAC as manufacturer-quoted list prices to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

Since our last report, the price at which albuterol was available to the supplier community decreased, while the Medicare reimbursement amount remained the same. In 2001, we calculated that the median price of albuterol through wholesaler/distributors and GPOs was $0.08 per mg, 33 percent higher than the 2003 price of $0.06 per mg. In addition, manufacturer-reported WACs also decreased from a median of $0.11 per mg in 2001 to $0.08 in 2003.

If Medicare were able to use prices available to the supplier community as a basis for albuterol reimbursement, the program and its beneficiaries would save millions of dollars a year.

The Medicare reimbursement amount for albuterol was over nine times higher than the median price available to VA.

In 2003, the median Federal Supply Schedule price available to VA for albuterol was $0.05 per mg. In comparison, Medicare reimbursed nine times more ($0.47 per mg) for the same amount of the drug. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug.

Both the VA Federal Supply Schedule price and the Medicare reimbursement amount for albuterol have remained constant since our previous report (*Excessive Medicare Reimbursement for Albuterol)* in 2002 (based on 2001 data). The 2003 VA price, however, was still over 50 percent lower than it was in 1998 ($0.11 per mg), while the Medicare price had not changed during the same 5-year period.

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high premium for albuterol. This report is part of a series of reports on albuterol which have consistently found that the published AWPs, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published AWPs, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for albuterol than they did several years ago. In addition, Medicare's total reimbursement for albuterol continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, albuterol is usually provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs, while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-ninth of Medicare's reimbursement amount is troubling.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including albuterol. Based on this new Act, Medicare will reimburse albuterol at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia Regional Office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

David Tawes, *Team Leader*

Cynthia Hansford, *Program Assistant*

Linda Frisch, Program Specialist

EXHIBIT 8

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicare Reimbursement of Prescription Drugs

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OFFICE OF INSPECTOR GENERAL

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OEI's Philadelphia Regional Office prepared this report under the direction of Robert A. Vito, Regional Inspector General, and Linda M. Ragone, Deputy Regional Inspector General. Principal OEI staff included:

REGION

David Tawes, *Project Leader*
Tara Schmerling, *Program Analyst*

HEADQUARTERS

Stuart Wright, *Program Specialist*
Linda Moscoe, *Technical Support Staff*

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EXECUTIVE SUMMARY

PURPOSE

This inspection compares Medicare reimbursement for prescription drugs to costs incurred by the Department of Veterans Affairs, the physician/supplier community, and Medicaid.

BACKGROUND

Medicare does not pay for most outpatient prescription drugs. However, Medicare Part B will cover certain prescription drugs under specific circumstances. Medicare and its beneficiaries paid $3.9 billion for prescription drugs in 1999. The Health Care Financing Administration (HCFA) requires its local carriers and four durable medical equipment regional carriers (DMERCs) to establish reimbursement amounts for covered drugs. In general, the Medicare reimbursement amount for a covered drug is 95 percent of the drug's average wholesale price (AWP). Of this amount, Medicare pays 80 percent while the beneficiary is responsible for a 20 percent copayment.

Each State Medicaid agency has the authority to develop its own drug reimbursement methodology subject to upper limits set by HCFA. Additionally, Medicaid receives rebates from drug manufacturers as required by Federal law. Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. Physicians and suppliers can purchase drug products through closed pharmacies, group purchasing organizations, wholesalers, and directly from manufacturers.

For 24 drugs with the highest total Medicare payments in 1999, we compared Medicare's current reimbursement amount for each drug to prices available to the VA and the physician/supplier community, as well as to Medicaid rebate amounts.

FINDINGS

Medicare and its beneficiaries would save $1.6 billion a year if 24 drugs were reimbursed at amounts available to the VA

After comparing the median Medicare reimbursement amount with the corresponding median VA acquisition cost for 24 drugs, we estimated that Medicare and its beneficiaries would save $1.6 billion a year if the Medicare reimbursement amounts for the drugs equaled prices obtained by the VA under the Federal Supply Schedule. The estimated savings represents 52 percent of the $3.1 billion in reimbursement that Medicare and its beneficiaries paid for these 24 drugs in 1999. The VA paid between 8

and 91 percent less than Medicare for the 24 drugs reviewed. Medicare paid more than double the VA price for 12 of the reviewed drugs.

Medicare and its beneficiaries would save $761 million a year by paying the actual wholesale price for 24 drugs

We estimated that Medicare payments for 24 drugs exceeded actual wholesale prices by $761 million a year. This represents 25 percent of the $3.1 billion Medicare and its beneficiaries paid for these drugs in 1999. Actual wholesale prices were between 6 and 84 percent below Medicare reimbursement amounts for the 24 drugs. Four of the drugs had median catalog prices that were less than half the Medicare amount. One of these drugs had a Medicare reimbursement amount more than six times higher than the median catalog price.

Medicare would save over $425 million a year on 24 drugs by obtaining rebates equal to those in the Medicaid program

We estimated that Medicare would save $429 million a year on the 24 reviewed drugs by collecting rebates equal to those negotiated by the Medicaid program. These rebates would lower Medicare spending on these 24 drugs by almost 15 percent.

Carriers are not establishing consistent drug reimbursement amounts for certain drugs

Although Medicare's reimbursement methodology states that drugs are reimbursed at 95 percent of AWP, we found differences in drug reimbursement amounts between local carriers. Six of the 21 drugs whose reimbursement amounts are set by local carriers had more than a 10 percent difference between the lowest and highest reimbursement amount. The most egregious was J0640 (leucovorin calcium), with one carrier reimbursing $17.51 and another reimbursing $35.47. The variation in reimbursement amounts was not present for the three drugs reimbursed by DMERCs.

RECOMMENDATIONS

The HCFA should reduce excessive Medicare drug reimbursement amounts

Despite numerous attempts by HCFA to lower Medicare drug reimbursement, the findings of this report illustrate once again that Medicare simply pays too much for prescription drugs. The published AWPs that Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers. We believe that HCFA's attempts to use the more accurate AWPs supplied by First Databank, publisher of a drug pricing compendium used by the drug industry, is a significant first step towards reimbursing drugs in a more appropriate manner. However, we believe that HCFA should continue to seek additional administrative and legislative remedies to reduce excessive drug reimbursement amounts.

We believe there are a number of options available to HCFA for implementing this recommendation, including: (1) continuing to collect more accurate average wholesale prices from drug pricing catalogs, (2) basing payment on physician/supplier acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, (4) creating a fee schedule for covered drugs based on Department of Veterans Affairs prices, and (5) utilizing the inherent reasonableness authority.

The HCFA should require all carriers to reimburse a uniform amount for each drug

We believe that the pricing differences among local carriers for individual drug codes is problematic. The amount which physicians and suppliers are reimbursed for drugs should not depend on which carrier they bill. The DMERCs have been able to adopt uniform pricing for the drugs which they cover, and we expect that local carriers should be able to do the same. In a 1997 report which noted similar problems, we recommended two options to correct pricing differences: (1) the HCFA could supply all carriers with list of average wholesale prices that it has determined represent each drug code, or (2) the HCFA could contract with a single entity to calculate drug reimbursement amounts and then distribute the amounts to each carrier. We continue to recommend that HCFA undertake one of these options.

Agency Comments

The HCFA concurred with our recommendation that reimbursement amounts for Medicare-covered drugs should be lowered, noting that the current AWP-based reimbursement method creates incentives for price inflation, distorts clinical decisions, and cheats taxpayers. The HCFA also explained that some providers now rely on inflated drug payments to cover other practice expenses. The HCFA believes that any price reductions need to take these expenses into account. Nevertheless, the HCFA strongly agreed that the payment of inflated drug prices is an inappropriate way to compensate practitioners and suppliers for inadequate reimbursement of other practice costs. The HCFA also agreed with our recommendation that Medicare carriers should be required to reimburse uniform amounts for covered drugs. The full text of HCFA's comments is presented in Appendix F.

TABLE OF CONTENTS